

SEP - 9 2011

**510(k) SUMMARY**  
**Titan Spine's Endoskeleton® TAS**

Date:	May 28, 2010	
Contact:	Kevin Gemas President 866-822-7800	Titan Spine, LLC Mequon Research Center 6140 Executive Dr., Suite A Mequon, WI 53092
Trade Name:	Endoskeleton® TAS	
Product Class:	Class II	
Classification:	21 CFR §888.3080 Orthosis, intervertebral body fusion device	
Product Codes:	OVD	
Panel Code:	87	

**Name of Device and Name/Address of Sponsor**

Titan Spine, LLC  
Mequon Research Center  
6140 W. Executive Drive, Suite A  
Mequon, WI 53092

**Common or Usual Name**

Intervertebral body fusion device

**Predicate Devices**

The Endoskeleton® TAS was shown to be substantially equivalent to legally marketed predicate devices. The predicate devices are the Endoskeleton TA Interbody Fusion Device (K080615) and the Stalif TT (K073109) and the BAK Lumbar device (P950002).

**Intended Use / Indications for Use**

The Endoskeleton® TAS Interbody Fusion Device is indicated for use in skeletally mature patients with Degenerative Disc Disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. Patients should have received 6 months of non-operative treatment prior to treatment with the devices. The device may be used with supplemental fixation. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). It is indicated to be use with autograft bone.

**Technological Characteristics**

The Endoskeleton® TAS is comprised of a variety of implant sizes to accommodate various patients' anatomy and pathology, and includes associated instrumentation. All implantable



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room -W066-G609  
Silver Spring, MD 20993-0002

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Titan Spine, LLC  
% Silver Pine Consulting, LLC  
Richard Jansen, Pharm.D.  
13540 Guild Avenue  
Apple Valley, Minnesota 55124

Re: K111626  
Trade/Device Name: Endoskeleton<sup>®</sup> TAS  
Regulation Number: 21 CFR 888.3080  
Regulation Name: Intervertebral body fusion device  
Regulatory Class: Class II  
Product Code: OVD  
Dated: August 24, 2011  
Received: August 25, 2011

Dear Dr. Jansen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

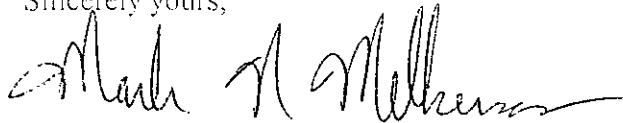
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson", with a long horizontal flourish extending to the right.

Mark N. Melkerson  
Director  
Division of Surgical, Orthopedic  
and Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

### Indications for Use Statement

510(k) Number (if known): K111626

Device Name: Endoskeleton® TAS

#### Indications for Use:

The Endoskeleton® TAS Interbody Fusion Device is indicated for use in skeletally mature patients with Degenerative Disc Disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. Patients should have received 6 months of non-operative treatment prior to treatment with the devices. The device is a standalone system intended to be used with the bone screws provided and requires no additional supplementary fixation. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). It is indicated to be use with autograft bone.

Prescription Use   v    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use             
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)

Division of Surgical, Orthopedic,  
and Restorative Devices

510(k) Number K111626